

MAY 21 2002

**V. 510(k) Summary****Submitter**

MedAmicus, Incorporated  
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Minneapolis, MN 55447  
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**Date Prepared**

February 15, 2002

**Trade Name**

MedAmicus Axia RSN™

**Common Name**

Catheter Introducer

**Predicate Device**

MedAmicus Guidewire Introducer Safety Needle, K011085  
Boston Scientific Corporation Introducer Sheath and Dilator, K971165

**Device Description**

The MedAmicus Axia RSN™ is a single use device for percutaneous introduction of guidewires, or similar devices, up to 0.038 inches in diameter. The device is packaged as either sterile single units or as part of a kit. The device is designed with a shield as part of the safety needle mechanism to aid in the prevention of needle stick injuries. The needle of the device is retracted into the shield by pushing the button prior to removal of the device off the guidewire, or other device, and out of the body. After retraction, the shield covers the needle tip. The device is disposed of according to routine procedure in a sharps container.

**Intended Use**

The MedAmicus Axia RSN™ is intended to minimize needle stick injuries when used for percutaneous introduction of guidewires, or similar devices.

**Technological Characteristics**

The device is technologically equivalent to other introducers and safety needles. The safety feature, which forms an integral part of this device, is a retractable needle mechanism that helps to minimize the risk of needle stick injuries.

**Summary of Studies**

No new testing was performed for the device as the only change being made is to the Indications for Use. All testing previously summarized in K011085 remains applicable.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 21 2002

Mr. Dennis S. Madison  
Vice President, Regulatory Affairs  
MedAmicus, Inc.  
15301 Highway 55 West  
Minneapolis, MN 55447

Re: K020563  
MedAmicus Axia RSN™  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer.  
Regulatory Class: Class II (two)  
Product Code: 74 DYB  
Dated: February 18, 2002  
Received: February 20, 2002

Dear Mr. Madison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

Page 2 – Mr. Dennis S. Madison

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", written in a cursive style.

Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## VI. Indications for Use

510(k) Number (if known): Not Assigned

K020563

Device Name: MedAmicus Axia RSN™

Indications for Use: The MedAmicus Axia RSN™ is intended to minimize needle stick injuries when used for percutaneous introduction of guidewires or other devices.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)


Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-The-Counter Use ☐

(Per 21 CFR 801.109)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K020563